

MAR 1 9 2001

K003584

SECTION 8  
510(K) SUMMARY

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FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Micromass Inc. is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Micromass Inc. chooses to submit a summary of information respecting safety and effectiveness.

➤ COMMON/USUAL NAMES: Mass Spectrometer

➤ TRADE/PROPRIETARY NAME: NeoLynx™

➤ CLASSIFICATION NAME &  
DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Phenylalanine Test System	JNB or JNC	862.1555
Tyrosine Test System	CDR	862.1730

➤ DEVICE PANEL/BRANCH: Clinical Chemistry (CH)  
Clinical Chemistry

➤ OWNER/OPERATOR: Micromass UK Limited  
Floats Road  
Wythenshawe, UK  
M23 9LZ  
Owner/Operator No. 9040671

➤ CONTACT PERSON: Daniel J. Dillon, Director, Regulatory Affairs

INDICATIONS FOR USE

The NeoLynx™ Screening Application Manager is indicated for the measurement of phenylalanine and tyrosine in neonatal blood samples for the purpose of screening for phenylketonuria.

CONTRAINDICATIONS

None.

POTENTIAL COMPLICATIONS

None.

### SUBSTANTIAL EQUIVALENCE

Micromass Inc. believes that the NeoLynx™ Screening Application Manager is substantially equivalent to the currently-marketed BBL® PKU Test Kit, Quantase™ Phenylalanine Screening Assay Test Kit, Astoria-Pacific Tyrosine 50-Hour Test Kit, and the Quattro LC Tandem Mass Spectrometer

### PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on NeoLynx™ Screening Application Manager to verify its safety and performance. Software development information was included to provide additional assurance of device performance.

### CONCLUSION

Micromass Inc. believes that NeoLynx™ Screening Application Manager is substantially equivalent to the currently-marketed BBL® PKU Test Kit, Quantase™ Phenylalanine Screening Assay Test Kit, Astoria-Pacific Tyrosine 50-Hour Test Kit, and the Quattro LC Tandem Mass Spectrometer. Micromass Inc. has presented laboratory testing and software development information. The information presented provides assurance that the NeoLynx™ Screening Application Manager will meet the minimum requirements that are considered acceptable for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 19 2001

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Micromass Inc.  
c/o: Mr. Daniel J. Dillion  
Waters Corporation  
34 Maple Street  
Milford, MA 01757

Re: K003584  
Trade Name: NeoLynx™ Screening Application Manager  
Regulatory Class: II  
Product Code: JNB  
Regulatory Class: I reserved  
Product Code: CDR  
Dated: March 5, 2001  
Received: March 8, 2001

Dear Mr. Dillion:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

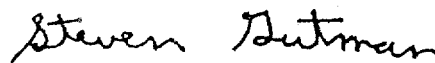
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

SECTION 1  
INDICATIONS FOR USE

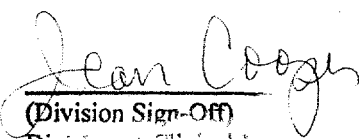
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510(k) Number: K003584 To Be Determined

Device Name: NeoLynx™ Screening Application Manager

Indication for Use:

The NeoLynx™ Screening Application Manager is indicated for the measurement of phenylalanine and tyrosine in neonatal blood samples for the purposes of screening for phenylketonuria. Measurements of phenylalanine are used in the diagnosis and treatment of inherited phenylketonuria which, if untreated, may cause mental retardation. Measurements of tyrosine can be used as adjunct to the measurement of phenylalanine in detecting inherited phenylketonuria. This quantitative test is conducted on dried bloodspot samples..

  
(Division Sign-Off)

Division of Clinical L.

510(k) Number

K003584

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_